



**Guidance for Selecting Toxicity Reference
Values for Alberta Tier 1 and Tier 2 Soil and
Groundwater Remediation Guidelines**

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Glossary

Acute effect: An effect resulting from exposure by the oral, dermal or inhalation route for short periods of time, usually 24 hours or less. In the context of this document this also includes receptor safety.

Adverse effect: Impairment of or damage to the environment or human health. It is noted that this is a limited scope from the definition of adverse effect; namely, “Impairment of or damage to the environment, human health or safety or property.” (*Environmental Protection and Enhancement Act*, (GOA, 2006)). Safety and property are not addressed in the context of this document.

Alberta Tier 1 Soil and Groundwater Remediation Guidelines: Generic remediation guidelines that are developed using conservative assumptions to be protective of environmental receptors. They can be used at most sites where a contaminant has been released to soil and/or groundwater without modification. The guidelines are maintained by Alberta Environment and Parks.

Alberta Tier 2 Soil and Groundwater Remediation Guidelines: Guidelines that apply the same protection objectives as Tier 1 but allow for modification of the Tier 1 guideline values based on site-specific conditions. The guidelines outline a process for modification of the Alberta Tier 1 guidelines but do not specify exact risk-based values. The guidelines are maintained by Alberta Environment and Parks.

Assessment endpoint: A specific characteristic of an ecological receptor or receptor group that is considered important enough to be protected and used in determining ecological risk. It may also have a clearly defined spatial or temporal aspect.

Chronic effect: An effect that occurs to a human or ecological receptor as a result of repeated or long term exposures to a hazardous contaminant.

Contaminant: A substance that is present in an environmental medium in excess of natural background concentration (CCME, 2006).

Contaminant of Potential Concern (COPC): Any contaminant which may or may not be causing an adverse effect to human and ecological receptors at a site.

Dose: The quantity of something that an organism may be exposed to.

Drinking Water Guidance Value (DWGV): A guidance value developed by Health Canada. It is based on limited scientific information available at the time of the request, and not on a thorough review of all existing studies. Drinking Water Guidance Values apply to water intended for human consumption.

Ecotoxicological Benchmark (EB): Concentrations of chemicals in ambient media (e.g., soil, plants, sediment, water, air, invertebrates, domestic animals and wildlife) that are believed to represent acceptable concentrations with respect to the valued ecosystem component, receptor of concern or assessment endpoint.

Non-threshold contaminant: A contaminant which shows effects at virtually all levels of exposure. Any exposure to these contaminants will result in some level of risk. Most, but not all, carcinogens are generally regarded as non-threshold acting contaminants.

Primary reference source: A literature source that is used to determine an acceptable toxicity reference value for a contaminant of potential concern at a contaminated site in Alberta. If a source is not listed in this document, it cannot be used as a primary source but may be valid as a secondary reference source.

Primary scientific study: Original material that has not been filtered through interpretation or evaluation by a second party.

Receptor: The individual organism, species, population or community that may be exposed to contaminants.

Receptor of Concern (ROC): A receptor that is exposed to and may be adversely affected by contaminants or other stressors.

Reference Dose (RfD): The maximum acceptable oral dose of a toxic substance to a human receptor. An estimate of a daily oral exposure to the human population that is likely to be without an appreciable risk of deleterious effects during a lifetime.

Risk Specific Concentration (RSC): The concentration of a chemical that a person breathes in every day over a lifetime expected to lead to a specified cancer risk for a chemical that is analyzed through a non-threshold carcinogenic approach. In Alberta, a 1 in 100,000 risk factor is used to calculate the cancer risk specific dose/concentration for the purpose of assessment of risk for contaminated sites.

Risk Specific Dose (RSD): The amount of a chemical that a person is exposed to via oral or dermal pathways over a lifetime expected to lead to a specified cancer risk for chemical that is analyzed by a non-threshold carcinogenic approach. In Alberta, a 1 in 100,000 risk factor is used to calculate the cancer risk specific dose/concentration for the purpose of assessment of risk for contaminated sites.

Scientific Working Group on Contaminated Sites in Alberta (SWGCSA): A formal multi-agency point of contact to build consensus and to address questions regarding the science surrounding risk assessment relating to contaminated sites in Alberta.

Secondary reference source: A literature source that may be used to determine an acceptable toxicity reference value where there is no information available from any of the accepted primary reference sources.

Stressor: Any physical, chemical or biological factor that will cause stress to an organism.

Subchronic effect: An effect resulting from repeated exposure by the oral, dermal, or inhalation route for more than 30 days, up to approximately 10% of the lifetime of a human or ecological receptor.

Tertiary reference source: A literature source that may be used to determine an acceptable toxicity reference value where there is no information available from any of the accepted primary or secondary reference sources.

Threshold contaminant: A contaminant for which there is a dose/concentration below which no adverse environmental or health effects are expected to occur.

Tolerable Concentration (TC): The concentration of a chemical in air to which a person may be exposed over a lifetime with no expected adverse effects. A tolerable concentration can only be determined for threshold contaminants.

Tolerable Daily Intake (TDI): The daily amount of a chemical that has been assessed safe for human exposure over a lifetime. A tolerable daily intake can only be determined for threshold contaminants.

Toxicological Reference Value (TRV): An exposure concentration or dose of a contaminant of potential concern that is not expected to cause an unacceptable level of effect in a receptor of concern. As such, a toxicity reference value may consist of a tolerable daily intake, tolerable concentration, risk specific concentration, risk specific dose, reference dose or Ecotoxicological benchmark for a chemical of potential concern.

Valued Ecosystem Component: An element of the environment that has scientific, economic, social or cultural significance.

Abbreviations

AENV – Alberta Environment

AEP – Alberta Environment and Parks

AER – Alberta Energy Regulator

AH – Alberta Health

AHS – Alberta Health Services

ATSDR – Agency for Toxic Substance and Disease Registry

Cal EPA – California Environmental Protection Agency

CCME – Canadian Council of Ministers of the Environment

CEQG – Canadian Environmental Quality Guideline

COPC – Contaminant of Potential Concern

DWGV – Drinking Water Guidance Value

EB – Ecotoxicological Benchmark

ECHA – European Chemicals Agency

EPEA – Environmental Protection and Enhancement Act

ESRD – Alberta Environment and Sustainable Resource Development

GOA – Government of Alberta

HC – Health Canada

ICS – Incident Command System

IRIS – Integrated Risk Information System

NOAEL – No Observed Adverse Effect Limit

PCE - Tetrachloroethylene (Perchloroethylene, Tetrachlorethene)

PHA – Public Health Act

RAIS – Risk Assessment Information System

REACH - Registration Evaluation Authorization & restriction of Chemicals

REDA – Responsible Energy Development Act

RIVM - Netherlands National Institute of Public Health and the Environment

ROC - Receptor of Concern

RfD - Reference Dose

RSC - Risk Specific Concentration

RSD - Risk Specific Dose

SWGCSA - Scientific Working Group on Contaminated Sites in Alberta

TC - Tolerable Concentration

TDI - Tolerable Daily Intake

TRV - Toxicological Reference Value

USEPA – United States Environmental Protection Agency

WHO – World Health Organization

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1. Introduction

This document presents the Government of Alberta (GOA) guidance for selecting acceptable risk-based Toxicological Reference Values (TRVs) for managing contaminated sites in Alberta. It has been developed through general agreement through the Scientific Working Group on Contaminated Sites in Alberta (SWGCSA), whose membership includes Alberta Environment and Parks (AEP), the Alberta Energy Regulator (AER), Alberta Health (AH) and Alberta Health Services (AHS).

This document describes the process used to select TRVs for use in deriving the soil and groundwater remediation guidelines recommended in the Alberta Tier 1 Soil and Groundwater Remediation Guidelines (Alberta Tier 1 Guidelines) (AEP, 2016a), and the Alberta Tier 2 Soil and Groundwater Remediation Guidelines (Alberta Tier 2 Guidelines) (AEP, 2016b). It applies when developing and evaluating options for assessment and management of contaminated lands in Alberta. The desired outcome is to provide a mechanism for consistent selection and interpretation of TRVs within the Alberta Tier 1 and Tier 2 Guidelines (AEP, 2016a,b) when developing risk-based remediation objectives/guidelines for Contaminants of Potential Concern (COPCs).

The SWGCSA is a formal multi-agency point of contact to build consensus and to address questions regarding the science surrounding risk assessment relating to contaminated sites in Alberta. Where decisions are required on reference sources for TRVs, they will be channeled through this group.

The document was developed with four main objectives in mind:

1. To provide guidance for updating existing TRVs in the Alberta Tier 1 and Tier 2 Guidelines (AEP, 2016a,b)
2. To consider chemicals where the TRVs do not exist within Alberta Tier 1 and Tier 2 Guidelines
3. To provide a consistent agreed upon message between AEP, AER, AH and AHS in relation to the interpretation and application of TRVs within the context of the Alberta Tier 1 and Tier 2 Guidelines (AEP, 2016a,b)
4. To provide risk assessors with a consistent approach to the selection and application of TRVs in the risk assessment process

A TRV is an exposure concentration or dose of a contaminant of potential concern (COPC) that is not expected to cause an unacceptable level of effect.

The approach, defined and outlined in this document, should be followed for any information that is submitted to the department (AEP) or regulatory agency (AER) related to substance releases to soil or groundwater that are not covered by provincial regulation (EPEA, REDA), guidelines (Alberta Tier 1 and Tier 2) or prior approval.

2. Application

The guidance on TRVs presented in this document will be adopted in circumstances which may include

- updating TRVs for current Alberta Tier 1 and Tier 2 Guidelines (AEP, 2016a,b);
- chemicals of potential concern that are not directly covered in the Alberta Tier 1 and Tier 2 Guidelines (AEP, 2016a,b); or where TRVs are not well characterized in existing literature;
- where Federal or Provincial guidelines are not based on the same toxicological data, have alternative safety or uncertainty factors, or for any other reason do not have equivalent guideline values;
- where consideration must be given to a more sensitive land use (human or ecological) than is already anticipated in the Alberta Tier 1 Guidelines (2016a);
- where exposure control scenarios or site specific risk management scenarios are adopted that lead to different assumptions (e.g. acute effects or subchronic effects vs chronic effects) than those presented in the Alberta Tier 1 and Tier 2 Guidelines (AEP, 2016a,b);
- where there are large scale impacts that may not be appropriately accounted for under the Alberta Tier 1 and Tier 2 Guidelines (AEP, 2016a,b) (e.g. large scale impacts that may impact landscapes, ecodistricts waterbodies or watersheds that are not appropriately accounted for in effects calculations at the Tier 1 level); and,
- For emerging issues that had not been anticipated in the development of exposure pathways, receptors or endpoints used in the Alberta Tier 1 and Tier 2 Guidelines (AEP, 2016a,b).

Alberta Tier 1 Soil and Groundwater Remediation Guidelines (AEP, 2016a) are generic remediation guidelines that are developed to protect sites for the most sensitive populations and can, therefore, be used at most sites where a substance has been released to soil and groundwater without modification.

Often under more sensitive land use scenarios consideration must be given to traditional land use activities (e.g., hunting, fishing, and gathering to provide traditional food for human consumption). Under these scenarios, it may be necessary to consider effects to specific species or food chain consumptions that are not considered in generic criteria but the same principles used in developing the Tier 1 and Tier 2 Guidelines (AEP, 2016a,b) can be applied.

3. Regulatory Context

This document describes requirements under Part 5, Substance Release in the *Environmental Protection and Enhancement Act* (EPEA), (GOA, 2006). It relates specifically to Sections 111, Manner of Reporting, and 112, Duty to take Remedial Measures. The information in this document will form the basis of decisions for risk-based endpoints for releases to soil and groundwater that may cause an adverse effect. As such, it will form the basis for updating the TRVs for Alberta Tier 1 and Tier 2 Guidelines (AEP, 2016a,b).

This document will also be applied in a similar manner to energy resource activities under the *Responsible Energy Development Act* (REDA) (GOA, 2014) as it applies to substance releases to land or groundwater that are in excess of those prescribed in regulation or approval. Similarly, this document will provide rationale for assessing risk to human health under the *Public Health Act* (PHA) (GOA, 2015) where the provisions overlap with those covered under Part 5 of the *EPEA*.

This document is not intended to provide information regarding regulatory requirements outside of Part 5 of the *EPEA* or enforcement actions for non-compliance.

While the principles outlined in this document may be similar to the assessment of other media (e.g., drinking water, freshwater aquatic life), endpoints developed for these specific media fall outside the scope of this document. Similarly, Environmental Impact Assessments (EIAs) are also out of scope as they are covered under a different part of the *EPEA* and EIA requirements will need to be consistent with that part of the Act. Similarly, naturally occurring substances that may cause adverse effect to human health may be managed under provisions in the PHA.

4. Target Audience

The information in this document will be used by regulators for determining acceptable endpoints for risk assessments related to substance releases to soil or groundwater that are not covered by provincial regulation (*EPEA*, REDA), guidelines (Alberta Tier 1 and Tier 2) or prior approval.

This document also provides guidance for proponents, consultants, and other stakeholders on choosing the most appropriate TRVs for COPCs within the risk assessment process. However, application of the principles in this document requires a specific set of professional skills. It is recommended that this document only be used by qualified professionals with an in-depth knowledge of Alberta Acts, Guidelines and Regulations related to contaminated sites and substance releases to soil or groundwater that are not covered in regulation or approval.

Human health risk assessment guidance for EIAs in Alberta can be found at:

<http://www.health.alberta.ca/documents/Health-Risk-Enviro-Impact-Guide-2011.pdf>

A TRV is defined very broadly in this document. A TRV is inclusive of a Tolerable Daily Intake (TDI), Tolerable Concentration (TC), Risk Specific Concentration (RSC), or Risk Specific Dose (RSD), Ecological Benchmark (EB).

5. Reference Types

There are several TRV reference sources from recognized regulatory agencies and literature sources available. The SWGCSA chose to classify reference sources as one of three types:

1. Primary
2. Secondary
3. Tertiary

Primary reference sources are sources that have been previously agreed upon by all members of the SWGCSA (outlined in section 5.1.1). Updates to primary reference sources will trigger revisions so that the Alberta Tier 1 and Tier 2 Guidelines (AEP, 2016a,b) remain up to date and relevant.

Secondary reference sources are sources that are used when there is no information available from any of the accepted primary sources. Secondary reference sources will not be directly incorporated into the Alberta Tier 1 and Tier 2 Guidelines (AEP, 2016a,b) except under the process outlined in this document. The utilization of an alternate TRV where primary and/or secondary sources exist will only be considered with strong justification and rationale based on the criteria outlined in this document.

Tertiary reference sources are used when there is no information available from any of the accepted primary and secondary reference sources. Tertiary reference sources are not used in the development of the Alberta Tier 1 and Tier 2 Guidelines (AEP, 2016a,b). They may be used under exceptional circumstances in the development of site specific risk objectives where there is no information from primary and secondary reference sources. Typically, development/selection of a TRV from tertiary reference sources will require a development of a full scientific rationale. Some exceptions may be made for the interim management of COPCs where necessary.

It is recognized that all reference sources may use different protocols or procedures in the development of a TRV. While information in this document may be used to select a reference source for use in Alberta by the SWGCSA, it is not used to modify information that is available within the reference sources.

Once chosen, a reference source (primary or secondary) is to be adopted in its entirety when developing the Alberta Tier 1 Guidelines.

5.1 Primary Reference Sources

5.1.1 Primary Reference Sources for Use in Alberta

The following sources of information can be used as primary references for the selection of TRVs for use in developing Alberta Guidelines. The list is in order of preference. Subject to conditions noted in sections 5.1.3, 6.1 and 6.3 of this document, if there are disagreements between primary reference sources, documents that are ranked higher in this list will be used as preferential sources of information:

1. Primary Documents for use in Alberta
 - a. Alberta Tier 1 and Tier 2 Soil and Groundwater Remediation Guidelines (AEP, 2016a,b)¹
 - b. Alberta Environmental Quality Guidelines for Surface Water in Alberta (for surface water and sediment guidelines related to aquatic life, recreation and aesthetics, and agriculture)²
 - c. Other documents adopted by the Province of Alberta that are in keeping with criteria for primary reference sources as outlined in this document
2. Primary Sources
 - a. Health Canada (for human health based endpoints)³
 - b. Canadian Council of Ministers of the Environment (CCME) Canadian Environmental Quality Guidelines (CEQGs)
 - c. Environment Canada (for ecological based endpoints)
 - d. United States Environmental Protection Agency (USEPA) Integrated Risk Information System (IRIS; for human health based endpoints)
 - e. USEPA Office of Pesticide Programs (for pesticides only; can supersede IRIS)

¹ The Alberta Tier 1 Soil and Groundwater Remediation Guidelines do not meet the principles outlined in this document for primary reference sources but references used in developing tables in Appendix C of the guidelines do. The Alberta Tier 1 Soil and Groundwater Remediation Guidelines will be updated based on information from other primary reference source documents listed here. It is included as a primary document in this list to ensure that its importance is recognized for management of sites in Alberta.

² The Alberta Water Quality Guidelines for Alberta Surface Waters have been developed based on primary reference materials that are consistent with the principles outlined in this document. The guidelines themselves do not represent original sources of information. They are also considered a primary document.

³ Health Canada human health based endpoints that meet the criteria laid out in section 5.1.3 are considered primary source documents. Other documents that do not meet these criteria would not be considered for direct inclusion but could be considered under secondary sources or under exceptions where needed. For instance, Health Canada Drinking Water Guidelines and Health Canada Toxicological Reference Values meet this standard and are considered primary sources. Other Health Canada sources that would be produced outside a public, peer reviewed process (e.g. Health Canada Drinking Water Guideline Value DWGV) would be considered under secondary reference sources.

5.1.2 Mechanism for Updating the List of Primary Reference Sources

In order for the adoption of a new primary reference source in Alberta or for the primary reference source document ranking to be changed, information will need to be reviewed and accepted by the SWGCSA as outlined in section 5.1.3.

When a new primary reference source is added to the list, it will be ranked within the list of other agencies and reasons for the decision will be documented as outlined in subsequent sections. Where an agency document that is currently selected as a primary reference source needs to be removed from the list or adjusted within the list, the decision will be reviewed based on the guidance of this document and the reasons for removal or adjustment will be documented. Alberta Environment and Parks will house the central repository of all documents.

5.1.3 Criteria for Selection of Primary Reference Sources

Requirement for Implementation of Alberta Specific Guidelines

Where there is a document that has been developed by the GOA for assessment of sites under Part 5 of *EPEA* or for assessment of the potential for adverse effect(s), which specifies a TRV for a given media or receptor, this value will be preferentially used before other sources. Where there is a conflict between GOA documents, the most recent version should be applied to the assessment and adopted by the department or regulatory agency.

Required Criteria for Selection of Primary Reference Sources Outside of Alberta

For other jurisdictions, the following features are required to be nominated as a primary reference source.

1. In all cases, the level of protection developed by the agency must offer the same or better level of protection required by Alberta policy or it must be modified to ensure the same level of protection inherent to the value. For instance, when evaluating carcinogenic compounds, Alberta applies a risk specific dose based on a potential increase of 1×10^{-5} risk. Values that are calculated using greater risk would have to be adjusted to accommodate this risk factor before being adopted in Alberta.
2. The agency deriving a TRV must have regulatory authority or have been granted responsibility for developing guidance from an agency that has regulatory authority over an aspect of contaminated sites or receptors that are used in developing standards for contaminated sites.
 - a. In the instance where an agency has limited authority over specific pathways or receptors, they can be used as an authority for that area but not for other areas that may be related to contaminated sites. For instance, the agency may have authority over development of drinking water guidelines or surface water quality guidelines and can be used as an authority for those endpoints. However, this information will not automatically be used for the development of criteria for other pathways or receptors.
 - b. Notwithstanding clause (a), information supplied in the review may be used to guide development of appropriate endpoints for pathways and receptors other than the scope of the agency's jurisdictional authority if;
 - i. The agency information can be considered to be more defensible than the current primary source for the purpose of developing guidelines for other pathways and

receptors based on one or more principles outlined in section 6.1 of this document; and,

- ii. The information has been reviewed and approved for implementation as outlined in the Alberta Tier 1 Guidelines (AEP, 2016a).
3. For instance, in the example given in clause 2a. , the TRV the agency used in development of the drinking water quality guideline may be applied to calculate the human health direct contact guideline if it has been evaluated and accepted by the working group under clause 2b. The agency must be national or international in scope.
4. The agency must have clearly defined and published protocols for appraising and using data from primary scientific studies to calculate a TRV.
5. The agency must use a public peer review process.
6. A scientific rationale detailing the reasons for the decision must be publicly available.
7. Documents must be published in final form before being accepted as a primary reference source in Alberta.
8. The agency is committed to reviewing previous decisions from time to time to ensure the decision remains relevant to future research findings or changes in policy.
9. The agency is committed to using a defined risk-based approach.

Other Criteria

The following comparative criteria were considered to add to the weight of evidence for inclusion or prioritization of a primary reference source. These criteria should not be used to eliminate references that meet the requirements of outlined in 5.1.1, but to indicate which references should be considered more authoritative for decision making in Alberta.

The following list can be used to rank documents in order of preference and relevance for use in Alberta; move a document from a primary reference source to a secondary reference source of information; or, from a secondary reference source to a primary reference source of information.

In making a decision regarding the classification of a reference source, the SWGCSA will consider

1. the level of participation that GOA representatives had in the development of protocols or procedures;
2. the level of participation that GOA representatives had in the setting priorities for substances to be reviewed;
3. the amount of influence that GOA representatives can have in the review of final documents;
4. the degree to which an agency's protocols or procedures are in keeping with best practices as accepted by other regulatory agencies;
5. the level of agreement between the protocols used by the agency in developing the TRV and the protocols that are accepted for use in Alberta; and,
6. the level of acceptance by other regulatory communities as to the validity of the information produced by the agency.

5.2 Secondary Reference Sources

There will be some need to consult secondary source documents when making decisions for COPCs where no Tier 1 guidelines exist. When a COPC is common at release sites in Alberta but there is no

primary reference source or where the primary reference source is not being maintained as current, a review of secondary reference sources may be required to ensure Alberta Tier 1 and Tier 2 Guidelines (AEP, 2016a,b) are up to date.

Where a COPC is not a common concern in Alberta, it may still be necessary to develop appropriate TRVs in support of a site specific risk assessment. This policy is outlined in the Alberta Tier 1 and Tier 2 Guidelines (AEP, 2016a,b) where there are no Tier 1 Guidelines available.

Secondary sources will not be ranked in order of preference. When a review of secondary reference sources is required, any supporting scientific rationale and technical literature on which these decisions are based must be conducted. Previous decisions by the GOA will be considered when available. Consultation between the agencies (AEP, AER, AH, and AHS) is required when

1. this is a new decision for a COPC that has not been previously addressed;
2. a source for an existing TRV becomes obsolete; or
3. this represents a change of policy for the COPC based on previous decisions at other sites.

Referral of the issue to the SWGCSA will fulfill the requirements of consultation with other departments.

5.2.1 Secondary Reference Sources for Use in Alberta

Secondary sources include (not in order of priority):

1. United States Environmental Protection Agency (USEPA) Provisional Peer Reviewed Toxicity Values
2. World Health Organization (WHO)
3. Other provincial toxicity reference values or guidelines for the medium of interest
4. Agency for Toxic Substances And Disease Registry (ATSDR)
5. Oak Ridge National Laboratory (under the US Department of Energy)
6. California Environmental Protection Agency (Cal EPA)
7. Other US State toxicological values or guidelines
8. Other international agencies that have a national mandate for protection of ecological or human health along the exposure pathway or receptor that is important to the assessment (e.g. Netherlands National Institute of Public Health and the Environment (RIVM), Registration Evaluation Authorization & restriction of Chemicals (REACH), European Chemicals Agency (ECHA), etc.)
9. Interim guidance values developed from national or international agencies that are recognized as primary reference sources

5.2.2 Criteria for TRV Selection from Secondary Reference Sources

In reviewing the information from secondary sources, the following will need to be considered:

1. Closeness of fit for the secondary reference source to the principles stated for primary reference source (section 5.1.1). Preference is given to documents that have a better fit to the stated principles.

2. Where available, consider accepting interim values, provisional peer-reviewed TRVs or other non-peer-reviewed guidance from what would otherwise be considered a primary reference source. Interim guidance from primary reference sources will be given preference to other secondary source documents where supporting rationale is available.
3. Similarity of the protocols used in their preparation of the document with the principles stated from the following recognized risk assessment guidance documents:
 - a. AEPs Alberta Tier 1 and Tier 2 Guidelines (AEP, 2016a,b)
 - b. CCME's A Protocol for the Derivation of Environmental and Human Health Soil Quality Guidelines (CCME, 2006)
 - c. CCME's A Protocol for the Derivation of Groundwater Quality Guidelines for Use at Contaminated Sites (CCME, 2015)
 - d. Health Canada Guidance Documents related to Human Health Risk Assessment
 - e. USEPA Guidance on Developing Ecological Soil Screening Levels (USEPA, 2005)
 - f. USEPA guidance for risk assessment
 - g. US Risk Assessment Information System (RAIS)
4. Availability of supporting scientific rationale. Preference will be given to secondary reference sources that
 - a. Have available protocols that outline selection criteria and can be compared against Alberta policy and;
 - b. Have publically available scientific rationale.
5. A jurisdictional review including a comparison between potential secondary reference sources must be made.
 - a. Ensure that studies or references used to develop a secondary reference source are up to date. If the information is out of date, it will need to be updated to ensure that the value from the secondary reference source is current.
 - b. If the value from a secondary reference source was developed as part of a site specific risk assessment, it must be included within the jurisdictional review and include a discussion with the relevant regulatory authority to ensure it is acceptable prior to use.
6. Consider that jurisdictions will have varying policy decisions on how to review and rank information within the jurisdiction. These decisions, for instance, can include application of uncertainty factors, selection of primary literature sources, decisions on route-to-route extrapolation, preparation of species sensitivity distributions, minimum data set requirements etc. While these types of decisions will influence the selection of the final secondary reference source under the preceding paragraphs, they should not be used to revisit the final decision made in the secondary reference source that is being reviewed.
7. Consider the date on which information was reviewed for the relevance to emerging or new science. This does not mean that newer information will automatically be preferred over older studies. It is noted that many newer studies ultimately rely on similar original data sets and methods as older documents. It is also noted that often older reviews are still using the same critical studies or information as newer reviews.
8. The rigour of independent peer review will need to be considered. Values that are based on more rigorous peer review will be preferred over values developed outside this process.

9. Where different sources are deemed comparable, the more conservative value should be taken in the absence of a primary reference source.
10. Values derived for the medium or exposure route of interest are preferred over route to route extrapolation(s) based on other forms of dose administration. For instance, for drinking water, studies based on exposure through drinking water would be preferable over gavage studies used to extrapolate results to the drinking water medium. Similarly, a value based on studies that are more closely related to the species or ecological system of interest is preferable to a value based on studies that require additional extrapolation. Epidemiological or population level studies are preferred over basic fundamental laboratory based animal toxicology studies that require extrapolation to this level. Similarly, selection of animal model or plant model should, as far as possible, be comparable to the human or ecological endpoint being assessed.

5.3 Tertiary Reference Sources

Tertiary reference sources will not be considered for the establishment of TRVs for Alberta Tier 1 and Tier 2 Guidelines (AEP, 2016a,b) outside of a full review and publication of a scientific rationale or supporting document by the SWGCSA. As such, this document will not detail the process outside of primary or secondary reference sources. It is, however, recognized, that in some cases information from primary and secondary reference sources will not be sufficient due to a lack of toxicological review for some COPCs.

In absence of primary or secondary information, it may be possible to conduct a full scientific review based on available literature and establish a TRV. Where this is conducted as part of a GOA review and leads to the publication of a peer-reviewed, scientific rationale, the value may be adopted as a final TRV for development of an Alberta Tier 1 Guideline.

6. Selection of TRVs for use in Tier 1 and Tier 2 Guidelines (or other documents)

6.1 Selection of TRVs Where More than 1 Primary Reference Source Exists

Where more than one primary reference source is available for a single substance, the following rules will apply to the selection of criteria from the primary reference sources:

1. For Alberta sourced documents, where the source on which the value is based has been reviewed and changed by the relevant Alberta department/agency, the value will be reviewed by the SWGCSA for

There are different types or designs of epidemiological studies. Not all are created equal as some are more robust than others. For example, randomized control trials are the gold standard of medical evidence. Case-control and cohort designs are stronger than cross sectional designs. These factors should be considered in determining evaluating the strength or relevance of the reference source.

inclusion in the guideline at the next review cycle. Until then, the current value, recorded in the Alberta Tier 1 and Tier 2 Guidelines (AEP, 2016a,b) will be accepted as valid unless an exception is made as outlined in section 6.4 of this document.

2. For all sources, the value from the highest ranked source in section 5.1.1 will take precedence.
3. Values developed for a specific pathway or receptor will take precedence over values that are not specific to that pathway or receptor. For instance, a TRV developed by Health Canada for a drinking water guideline will take precedence over a TRV developed by the CCME for the Domestic Use Aquifer pathway.
4. Values that are developed for a specific exposure route are preferable to those developed using route-to-route extrapolation(s). Where available, a value for a specific exposure route from a lower ranked document may be used in place of a value from a higher ranked document if it avoids the need for route-to-route exposure extrapolation(s). For instance, a value developed specifically for vapour inhalation, will take precedence for an inhalation TRV over a derived value calculated based on route-to-route extrapolation(s) from oral intake to inhalation.
5. Where the TRV is to be applied to a pathway or receptor other than the one for which it was developed, the TRV may be considered based on the following criteria:
 - a. It is unlikely that the original source or other primary sources will review the new information in the next five years and
 - i. Values are based on newer science or newer studies than were present in the original review; or,
 - ii. Values are based on newer, accepted, protocols or procedures than for the original study or review.
 - b. The value is reviewed and recommended by the SWGCSA.
 - c. The decision is documented as outlined in section 6.4 of this document.
6. For documents ranked lower on the primary reference list but representing a newer and more robust review for the same pathway/receptor, the reference may be considered based on the following criteria:
 - a. It is unlikely that the original source or other primary sources will review the new information in the next five years and
 - i. Values are based on newer science or newer studies than were present in the original review; or,
 - ii. Values are based on newer, accepted, protocols or procedures than for the original study or review.
 - b. The value is reviewed and recommended by the SWGCSA.
 - c. The decision is documented as outlined in the section 6.4 of this document.

6.2 Selection of TRVs from a Secondary Reference Source

A TRV from a secondary source may be accepted for inclusion in the Alberta Tier 1 and Tier 2 Guidelines (AEP, 2016a,b) based on the following reasons.

1. Values from a secondary reference source may be used to develop TRVs for inclusion in Alberta Tier 1 and Tier 2 Guidelines (AEP, 2016a,b) if there is no primary reference source available and it is demonstrated that:
 - a. There is a need for an Alberta Tier 1 Guideline (AEP, 2016a) based on multiple encounters to a particular COPC at Alberta sites.
 - b. It is unlikely that a primary reference source will review and develop guidance for the COPC within the next 5 years.
 - c. The value is reviewed and recommended by the SWGCSA.
 - d. The decision is documented as outlined in the section 6.4 of this document.

2. Values from a secondary reference source may be used to supersede a primary source document for inclusion in the Alberta Tier 1 and Tier 2 Guidelines (AEP, 2016a,b) if it is demonstrated that:
 - a. There is a public health or ecological concern that is not likely to be addressed by the existing TRV.
 - b. It is unlikely that a primary reference source will review the information and develop a new TRV within the next 5 years and
 - i. The value is based on the most recent, robust science available or is based on newer studies than were present in the original review, or
 - ii. The value is based on newer, accepted, protocols or procedures than for the original review.
 - c. The value is reviewed and recommended by the SWGCSA;
 - d. The decision is documented as outlined in section 6.4 of this document.

In specific circumstances (e.g., immediate or serious public health or ecological concerns) other sources (e.g., tertiary or out-ranked sources) may be used over, or in lieu of, a primary or secondary source. In these cases more review and consideration must be provided (see Section 6.3.2 and 6.3.3).

Secondary sources may be considered when a TRV is required but no primary source exists or existing primary sources are not adequate (see sections 5.2 and 6.1).

6.3 Exceptions Allowed

There is a need to respond to emerging issues as they appear but, at the same time, to maintain a consistent, regular process for updating TRVs for guideline development. This will help avoid public

uncertainty when dealing with contaminated sites. An exception is a deviation from the rules outlined in this document regarding acceptable sources for TRV development. This document recognizes the need to allow for these exceptions but also to ensure these decisions are reviewed for consistent application to guideline development where they are made.

6.3.1 Circumstances Where Exceptions May be Considered

The following circumstances may be considered in allowing for an exception as described above:

1. During an incident or event within the province that requires the use of the Incident Command System (ICS), an exception may be allowed under the direction of the incident commander⁴ or other authorized representatives. This document does not supersede any authority given to an incident commander to direct the nature of response to an event as it is evolving. Where direction is given, it will be followed during the duration of the event. The decision will be reviewed after the event.
2. New TRVs that have been released by a primary source agency but that have not yet been reviewed for inclusion in the Alberta Tier 1 and Tier 2 Guidelines (AEP, 2016a,b). Values would be considered interim until they can be reviewed by the SWGCSA for incorporation into the Alberta Tier 1 and Tier 2 Guidelines (AEP, 2016a,b).
3. Emerging issues that have not been assessed through the protocols used by the primary or secondary reference source used for the current TRV.
4. Identification of immediate or serious public health or ecological concerns.
5. Direction given by an Authority under legislation (e.g. Minister, Chief Medical Officer of Health).
6. Objectives that are not typically covered within Alberta Tier 1 and Tier 2 Guidelines but for which there are public health or environmental concerns that have been raised (e.g. Alberta Ambient Air Quality Objectives).

Tertiary sources may be considered only with a thorough scientific review and documentation (see Section 5.3 and 6.4).

⁴ Under the Incident Command System (ICS), the incident commander provides overall leadership for the incident response or management of an incident or event. The incident commander delegates authority to others as the complexity of the incident or event dictates. The incident commander takes general direction from the agency of jurisdiction administrator or official and performs all major ICS command and general staff responsibilities unless the ICS functions are delegated and assigned.

6.3.2 Requirement for Review of an Exception

In all instances where an exception is made or direction is given to supersede an existing TRV or guideline, it will be considered an interim value only. Where an exception is made:

1. a review of the decision is required by the SWGCSA,
2. the SWGCSA will ensure that a rationale for the exception is published, and
3. the Alberta Tier 1 and Tier 2 Guidelines will be updated accordingly.

Where the decision is made that is based on a change in the document ranking as outlined in section 5.1 or based on use of a secondary or tertiary source as outlined in sections 5.2 or 5.3, a record of the decision and rationale for the decision will be made as per section 6.4 of this document.

6.3.3 Guiding Principles When Adopting an Exception

It is not possible to list specific rules regarding exceptions since these will need to be made on a case by case basis. It is, however, possible to provide general guidance to be followed in creating an exception to guidance that already exists. When creating an exception, the following general principles must be followed:

1. Human health and ecological protection must be maintained and considered as the primary goal when adopting a TRV. With new developments in the field of toxicology, it will sometimes be demonstrated that the protection levels offered by existing TRVs are not sufficient to address the risks associated with a substance release to soil or groundwater. Where developments in the field of toxicology have demonstrated that the current TRVs are not protective, interim guidance will be necessary to ensure that protection is maintained.
2. Wherever possible the secondary goal is to maintain consistency in regulatory response as well as predictable transparency in adopting TRVs for contaminated sites management. When recommending a change to existing TRVs, it is important to remember that an unpredictable change to TRVs or risk assessment processes creates uncertainty for the public, site managers and regulatory agencies. While this should not lead to inaction when warranted, it is important to consider the level of uncertainty inherent in the TRV derivation process and whether the change in TRV is warranted given this level of uncertainty.
3. Recognize that there will always be some information gaps during the human health and ecological toxicity assessment process. All recommended guidelines have a certain amount of uncertainty inherently built into them. Generally, this uncertainty will lead to conservative assumptions in developing the guideline but this will not always be the case. Where a level of conservatism is already built into the original guidelines, this should be taken into account in determining whether there needs to be an immediate exception made or whether there is time to conduct a more thorough technical review before making a decision.
4. Consider public perception or stakeholder concerns. While it is important to consider the public perception in the regulatory process, it is also important to balance this against known and likely risks posed by the condition that is being investigated. While it is likely that the current guidance is sufficient to respond to circumstances presented in a stakeholder complaint. Public perception

on its own should not be enough to cause an immediate change to a TRV value outside a broader and thorough scientific and technical review of published data.

5. Consider lack of clear guidance or protocols from primary and secondary source agencies for a COPC. This would be true for a chemical that doesn't have established TRVs in any of the primary sources, where there is limited information on the toxicological response, or where there is an emerging issue that is not addressed by the primary or secondary reference source.
6. Consider the severity of the incident and the need for timely response. While a thorough examination of the chemical is preferable, this may not be possible during an emergency response to an incident or an incident where acute effects to human health or the environment are possible.
7. Consider the priorities and timing of any ongoing reviews by primary reference sources. It is always preferable, when possible, to have TRVs chosen based on the principles outlined in section 5.1. While it is necessary to consider the need to respond to emerging issues, where the level of risk that is presented by use of the current Alberta Tier 1 and Tier 2 Guidelines (AEP, 2016a,b) does not warrant an immediate response to the situation, it is preferable to wait for the review and adoption of new TRVs through a formal process.
8. Consider the weight of evidence and the response of other relevant agencies to similar concerns.

6.4 Requirement for TRV Guidance Documentation

The SWGCSA is responsible for ensuring that documented references are maintained for any changes to TRVs in the Alberta Tier 1 and Tier 2 Guidelines (AEP, 2016a,b) that are not consistent with the approved primary reference sources as outlined in section 5.1.1.

Where any updates to the Alberta Tier 1 and Tier 2 Guidelines (AEP, 2016a,b) are from primary reference sources, consistent with rules outlined in section 5, there is no requirement for review or documentation of changes. Source references and rationale will be available from the approved primary reference sources.

Where an exception is made that would supersede the normal selection process for the Alberta Tier 1 and Tier 2 Guidelines (AEP, 2016a,b) as outlined in section 5.1, the SWGCSA will ensure that documented rationale is provided to the SWGCSA within 1 year of the original decision.

A full scientific rationale is not required when

1. The decision required review and acceptance by the SWGCSA under section 6.1;
2. The SWGCSA use an existing secondary reference source as outlined in section 6.2; or,
3. An exception as outlined in section 6.3 is used, where a scientific rationale is available.

Rather a decision document will be produced that will include

1. A rationale, noting specific clauses in section 5.1, for deviation from the normal ranking procedure;
2. A rationale for acceptance of the reference source being chosen;
3. A comparison of the critical documents, showing the change in the TRV(s) that is being recommended; and
4. A brief summary of the review, noting the critical reasons why the new value was chosen.

Where a decision is part of a response to an incident or event, the decision will be reviewed and a final recommendation will be made based on a full review of the information. The review may agree with the response at the time of the incident, propose an alternative value based on the technical review, or propose to not use the decision to update the Alberta Tier 1 and Tier 2 Guidelines. Where the decision is not to incorporate the value into the Alberta Tier 1 and Tier 2 Guidelines, a published rationale is not needed.

Supporting documents will be made available to all government agencies. Where the document is used to update the Alberta Tier 1 and Tier 2 Guidelines (AEP, 2016a,b), a final rationale will be made available to the public by AEP.

Alberta Environment and Parks will be responsible for ensuring that the approved current version of this document is published and maintained on the AEP website.

6.5 Review of TRV Guidance Document

This guidance document will be reviewed every 5 years by the SWGCSA and updated as needed. Any new primary reference source for Alberta will need to be agreed upon by the SWGCSA. Where a department or agency wishes to update the primary reference sources, they will need to contact other agencies that have a regulatory stake in the decision. As much as possible, decisions will be based on consensus between the regulatory agencies. Where a new primary source of information is added to the list, it will be ranked within the list of current primary sources and reasons for the decision will be documented. If there is a difference of opinion that cannot be resolved, this will also be documented. Where an agency does not elect to participate and there is a need to update this document, this will be documented in the new provisions.

Where an agency document that is currently selected as a primary source of information needs to be removed from the list, the decision will be reviewed based on the same set of information provided within this document and reasons for removal will be documented.

7. References

Alberta Environment and Parks (AEP), 2016a. Alberta Tier 1 Soil and Groundwater Remediation Guidelines. March, 2016.

Alberta Environment and Parks (AEP), 2016b. Alberta Tier 2 Soil and Groundwater Remediation Guidelines. March, 2016.

Canadian Council of Ministers of the Environment (CCME), 2006. A Protocol for the Derivation of Environmental and Human Health Soil Quality Guidelines. PM 1332. Canadian Council of Ministers of the Environment, Winnipeg Manitoba.

Canadian Council of Ministers of the Environment (CCME), 2015. A Protocol for the Derivation of Groundwater Quality Guidelines for use at Contaminated Sites. PM 1533. Canadian Council of Ministers of the Environment, Winnipeg Manitoba.

Government of Alberta (GOA) 2006. *Environmental Protection and Enhancement Act*. Revised Statutes of Alberta 2000, Section E-12 with amendments in force as of May 24, 2006.

Government of Alberta (GOA), 2014. *Responsible Energy Development Act*. Statutes of Alberta, 2012, Chapter R-17.3.

Government of Alberta (GOA), 2015. *Public Health Act*. Revised Statutes of Alberta 2000, Chapter P-37.

United States Environmental Protection Agency (USEPA), 2005. Guidance for Developing Ecological Screening Levels. OSWER Directive 9285.7-55. U.W. Environmental Protection Agency, Office of Solid Waste and Emergency Response, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460.

United States Environmental Protection Agency (USEPA), 2001. Toxicological Review of Chloroform in Support of Summary Information on the Integrated Risk Information System (IRIS). United States Environmental Protection Agency. Washington, DC. October, 2001.

Appendix – Case Studies

1. Sulfolane

1.1 Summary

In March 2014, an incident occurred in which sulfolane was released from a gas plant, impacting a drinking water aquifer in the surrounding area. This triggered the development of a Health Canada Drinking Water Guidance Value (HCDWGV). The HCDWGV (HC, 2014a) used during this incident was different than the TRV for the same pathway published in the Alberta Tier 1 Soil and Groundwater Quality Guidelines (Alberta Tier 1 Guidelines) (ESRD, 2014). Based on this difference, a review of the information for sulfolane was required. Following the review, it was determined that no update to the Alberta Tier 1 Guideline was necessary at this time. Since no change was recommended, a published rationale was not required.

1.2 Rationale for the Review

1. During the incident in 2014, the sulfolane guideline that was chosen for the drinking water pathway was under the authority of the Incident Commander during an incident response.
2. Under section 6.3.1 point 1, the decision stands for the duration of the incident.
3. Health Canada is considered a Primary reference source under section 5.1. However, DWGVs may be developed as interim values by Health Canada when requested and when there is not an existing drinking water guideline. These values are not peer reviewed prior to publication. Therefore, under section 5.2.1, point 9, this would be considered a secondary reference source for the development of Alberta Tier 1 Guidelines.
4. In 2014, a guideline for drinking water was published in the Alberta Tier 1 Guidelines (ESRD, 2014) based on a CCME guideline (CCME, 2006). Under section 5.1, these are considered primary sources. Under section 6.3.1 point 1, this scenario required a technical review as the TRV chosen by the Incident Commander was different than the current Tier 1 value.

1.3 Key Findings

1. The Health Canada Drinking Water Guidance Value for Sulfolane (Health Canada, 2014a) would be considered a secondary source document. It is typically developed for the duration of an incident (usually 1 to 4 weeks in duration) and does not follow the same development process as the Guidelines for Canadian Drinking Water Quality, (Health Canada, 2014b) also developed by Health Canada. In particular, the short development time necessitates removal of any peer review process that is considered important to the selection of primary reference sources. This value would fall under section 5.2.1, point 9.
2. Since there was an existing primary source guideline for sulfolane, the inclusion of the HCDWGV (Health Canada, 2014a) needed to be reviewed for applicability under section 5.2.2, point 2. Under point 2, a rationale would need to be published if it were to be adopted for inclusion in the Alberta Tier 1 Guidelines.
3. Health Canada produced a DWGV for sulfolane as 0.04 mg/L for the drinking water pathway (Health Canada, 2014a).

4. In 2014, the Alberta Tier 1 Guideline of 0.09 mg/L for sulfolane (ESRD, 2014) for the same pathway was established. This was based on CCME (2006).
5. A review of the information provided in the two sources indicated the following
 - a. The Health Canada and CCME documents used the same critical study to determine the human health effects (HLS, 2001);
 - b. Health Canada (2014a) did include more recent information in their review than was available in 2006. However, this did not change the critical study used in both documents;
 - c. The newer information used by Health Canada did influence the decision. Health Canada used a benchmark dose method as referenced in ATSDR (2011). This was a departure from CCME (2006) where the study was used to develop a No Observed Adverse Effect Level (NOAEL). The use of the benchmark dose method could be considered cause for review as per section 6.2, point 2(b)(i);
 - d. The use of the benchmark dose method resulted in a higher critical concentration than the NOAEL value proposed by CCME (4.1 vs. 2.9 mg/kg bw-d); and
 - e. Health Canada applied a higher uncertainty factor for deficiencies in the database than was applied by CCME (10 vs 3). The combination of this and the higher critical concentration resulted in the lower overall TRV.
6. The difference between the approaches used by Health Canada and CCME fall under guiding principles 2 and 3, section 6.3.3 of this document. The changes proposed by Health Canada result from a differential interpretation of the uncertainty in deriving health based guidelines. The difference between the HCDWGV and the CCME value was not deemed to result in a lack of protection under guiding principle 1. Specifically, the *Drinking Water Guidance Value for Sulfolane* (Health Canada, 2014) document states that “occasional short-term exceedances above [0.04 mg/L] are not considered to be of concern.” Furthermore, the same document states that “DWGVs apply to water intended for human consumption, and do not replace or supersede existing guidelines or regulations in place.”
7. The sulfolane drinking water clean-up level is currently under review in the State of Alaska (awaiting the new US National Toxicology Program long-term toxicological studies). It was also noted during the review that both the USEPA and Health Canada are monitoring this review and that this may result in a more thorough review of sulfolane by one or both of the agencies. Both agencies represent a primary source of information for the Alberta Tier 1 Soil and Groundwater Remediation Guidelines (AEP, 2016).
8. It was therefore recommended that sulfolane is not updated in Alberta unless it was reviewed and updated by one of the primary source agencies.
9. No rationale and no further update was required at this time since the primary source was used to establish the Alberta Tier 1 Guideline (AEP, 2016).

1.4 References

Alberta Environment and Parks (AEP), 2016.. Alberta Tier 1 Soil and Groundwater Remediation Guidelines. March, 2016.

Agency for Toxic Substances and Disease Registry (ATSDR), 2011. Health Consultation – Sulfolane. Agency for Toxic Substances and Disease Registry, Division of and Environmental Medicine, Prevention, Response and Medical Support Branch, Emergency Response Team.

Canadian Council of Ministers of the Environment (CCME), 2006. Canadian Environmental Quality Guidelines for Sulfolane: Water and Soil. Scientific Supporting Document. Canadian Council of Ministers of the Environment, Winnipeg, Manitoba. 2006.

Alberta Environment and Sustainable Resource Development(ESRD), 2014. Alberta Tier 1 Soil and Groundwater Remediation Guidelines. March, 2014.

Health Canada, 2014a. Drinking Water Guidance Value for Sulfolane. Health Canada, March 17, 2014.

Health Canada, 2014b. Guidelines for Canadian Drinking Water Quality. Federal-Provincial-Territorial Committee on Drinking Water. October, 2014.

Huntingdon Life Sciences Ltd. (HLS), 2001. Sulfolane toxicity study by oral administration via the drinking water to CD rats for 13 weeks. Huntingdon Life Sciences Ltd, Huntingdon, United Kingdom.

2. Chloroform (Trichloromethane)

2.1 Summary

During an update of the Alberta Tier 1 Soil and Groundwater Quality Guidelines (ESRD, 2014) by the SWGCSA, it was noted that the derived non-threshold TRV for vapour inhalation was based on a previous USEPA value that was no longer being supported by the USEPA. While the USEPA had not updated their value at the time of the review, they had concern with the non-threshold approach for chloroform.

Based on the lack of continuing support for the use of a non-threshold approach in deriving vapour inhalation guidelines for chloroform, a review of the TRVs being used for chloroform was conducted.

As a result of this review, the toxicity reference values for chloroform were updated in the Alberta Tier 1 and Tier 2 Soil and Groundwater Quality Guidelines (AEP 2016a,b) in 2016.

Critical documents used to support this decision were considered primary reference sources. However, because the decision was based on newer documents that were lower in rank for the pathway being considered (vapour inhalation); a rationale was published by the SWGCSA. As the decision was based on published works from primary reference sources, a full scientific rationale was not required for this decision.

2.2 Rationale for the Review

1. The oral and inhalation threshold guidelines for chloroform published in the 2014 Alberta Tier 1 Soil and Groundwater Quality Guidelines (ESRD, 2014) were based on the USEPA IRIS, Toxicological Review of Chloroform, (USEPA, 2001).
2. An oral TDI of 0.01 mg/kg-day was obtained from the USEPA IRIS, Toxicological Review of Chloroform, (USEPA, 2001).
3. The Alberta Tier 1 inhalation TRV was derived directly from the USEPA oral threshold value. This assumes a direct extrapolation of the oral dose/response relationship to the inhalation route of exposure. The value for the inhalation pathway was determined to be 0.04475 mg/m³ (ESRD, 2014).
4. The Alberta Tier 1 guideline for drinking water was set at 0.093 mg/L based on the USEPA value of 0.01 mg/kg body weight/day (USEPA, 2001) and the standard default parameters used by Health Canada (Health Canada, 2010) for calculating drinking water.
5. The Alberta Tier 1 (ESRD, 2014) inhalation non-threshold unit risk factor (or slope factor) was set at (0.023 mg/m³)⁻¹. This was based on the posted information on from the USEPA (USEPA, 2001) at the time of the last review of chloroform.
6. At the time of the original publication of the Alberta Tier 1 Guidelines (AENV, 2007), there was a CCME soil quality guideline value (CCME, 1991) available. The soil quality guideline value was considered interim and was not based on a detailed risk-based review. Therefore, it was rejected as a primary source of information and the USEPA, 2001 source was adopted.
7. During an update to the Alberta Tier 1 Soil and Groundwater Quality Guidelines, it was noted that the USEPA had stopped supporting the use of a non-threshold approach for chloroform and that the use of this should be reviewed in the Alberta Tier 1 Guidelines. It was further noted that

the Health Canada Drinking Water Quality Guideline for Trihalomethanes (THM) (Health Canada, 2006) included chloroform and that much of the literature used to derive the THM guidelines (Health Canada, 2006) was based on chloroform. The 2014 Alberta Tier 1 Guidelines did not consider the Health Canada drinking water quality guideline for Trihalomethanes (Health Canada, 2006). (Since this would be considered a primary reference source that ranks higher than the USEPA source, this should be reviewed as part of the Tier 1 update.

8. The SWGCSA conducted the review in 2016.

2.3 Key Findings

1. In 2006, Health Canada published a Canadian drinking water guideline of 0.1 mg/L for trihalomethanes (Health Canada, 2006). The information used in deriving this guideline was directly applicable to chloroform.
2. It was noted during the most recent chloroform review that the chloroform value of 0.1 mg/L (Health Canada, 2006) for drinking water was not a health-based number. The health or risk-based guideline was established as 0.08 mg/L (Health Canada, 2006) based on chloroform toxicity information. As quoted in the report: *“Meeting a guideline of 80 µg/L for THMs in drinking water can present significant financial implications for treatment plants. As the increase in health risks from exposure to THMs at levels up to 100 µg/L is not expected to be significant, the Federal-Provincial-Territorial Committee on Drinking Water is establishing a Maximum Allowable Concentration of 0.10 mg/L (100 µg/L) for THMs in drinking water, based on an annual average. Utilities should make every effort to achieve concentrations as low as reasonably achievable without compromising the effectiveness of water disinfection.”*(Health Canada, 2006).
3. Based on the 2006 Health Canada review, a risk-based groundwater criterion for drinking water of 0.08 mg/L (Health Canada, 2006) for chloroform was recommended for Alberta Tier 1 Guidelines. This value was recommended as preferential to the USEPA value for the drinking water pathway since it is a higher ranking primary source document for the drinking water pathway as per section 5.1.1 of this Guidance Document. It was further noted that the use of this Health Canada, 2006 value did not require extrapolation from the oral route of exposure to the drinking water guideline as did the USEPA value (USEPA, 2001).
4. The review of the Health Canada Guidelines for Canadian Drinking Water: Trihalomethanes (Health Canada, 2006), and the USEPA position on the use of a threshold cancer approach for the oral pathway raised a number of issues with the use of the USEPA 1987 report for use of a non-threshold approach for the Tier 1 inhalation cancer TRV. It was therefore recommended that the Health Canada report be reviewed for inclusion in Alberta Tier 1 Guidelines for the direct human contact and vapour inhalation pathways as well, based on section 6.1 , point 6 because:
 - a. Both the USEPA and Health Canada allow for the use of a threshold approach for carcinogenic risk assessments under certain circumstances. Specifically, the USEPA notes that ... *“when the mode-of-action analysis based on available data indicates that the carcinogenic response is secondary to another toxicity that has a threshold, the margin-of-exposure analysis performed for toxicity is the same as is done for a non-cancer endpoint, an RfD for that toxicity may be considered in the cancer assessment”* (The Proposed Guidelines for Carcinogenic Risk Assessment, USEPA, 1996). This was the method used to determine the chloroform oral TRV by the USEPA (2001).

- b. In 2001, the USEPA noted that available evidence indicates that chloroform-induced carcinogenicity is secondary to cytotoxicity and regenerative hyperplasia, and that doses below the RfD do not result in cytolethality (and hence do not result in increased risk of cancer). Accordingly, an oral RfD of 0.01 mg/kg bw/day for protection against noncancer effects (including cytolethality and regenerative hyperplasia) was also judged to be protective against increased risk of cancer. Based on this, they recommended a threshold toxicity reference value for the oral and dermal routes of exposure (USEPA, 2001).
- c. The USEPA reserved the right to further review the inhalation route of exposure in 2001. The 2001 review retains previous information for the vapour inhalation pathway noted to be from previous information developed in 1987 (USEPA, 1987). In 2001, the USEPA noted that by doing so, the inhalation unit risk factor or slope factor did not incorporate newer data and did not incorporate the newer cancer assessment guidelines (USEPA, 2001). In the meantime, there was no compelling evidence presented that the mode of action along the inhalation pathway would be different than that observed for the ingestion pathway. It is also noted that in the interim, the USEPA had stopped supporting the 1987 non-threshold value.
- d. In the 2006 review (Health Canada, 2006), Health Canada notes a concern with use of the non-threshold approach. Specifically, that: *“The weight of evidence of genotoxicity, sex and strain specificity, and concordance of cytotoxicity, regenerative proliferation, and tumours is consistent with the hypothesis that cytotoxicity with a period of sustained cell proliferation likely represents a secondary mechanism for the induction of tumours following exposure to chloroform. This is consistent with a non-linear dose-response relationship for induction of tumours. This cytotoxicity is primarily related to rates of oxidation of chloroform to reactive intermediates, principally phosgene and hydrochloric acid. The weight of evidence for this mode of action is strongest for hepatic and renal tumours in mice and more limited for renal tumours in rats (Environment Canada and Health Canada, 2001). There has been little evidence to support other mechanisms of carcinogenicity, especially at low doses where cytotoxicity and cellular proliferation are not expected. Chloroform toxicity is clearly enhanced in rodents when administered in corn oil, compared with when it is received in drinking water, supporting the hypothesis that tumorigenicity of chloroform depends on the rate of its delivery to the target tissue and further suggesting that detoxification mechanisms must be saturated before the full carcinogenic potential of chloroform is realized (GlobalTox, 2002).”*
- e. Based on this information, Health Canada chose to classify chloroform as a Group 3, possibly carcinogenic under Health Canada (1994) categories (Health Canada, 2006). This classification supports use of a threshold approach only.
- f. The Health Canada Drinking Water Quality Guidelines are directly applicable to the drinking water pathway. These guidelines are not reviewed for the oral or dermal routes of exposure for direct contact with soil or for the indoor air route of exposure through the vapour inhalation pathway. However, in this instance, Health Canada reviewed information for these routes of exposure (e.g., multi-route exposure assessment) (Health Canada, 2006).

- g. Because of the risk of inhalation exposure to chloroform through showering, Health Canada, in developing a drinking water guideline, investigated risks along the inhalation route of exposure (Health Canada, 2006).
 - h. From Health Canada's work on the physiologically based pharmacokinetic modelling and relevant literature quoted, it was possible for Health Canada to establish the potential risk along the inhalation route of exposure along with the drinking water value (Health Canada, 2006).
 - i. The critical study (Heywood et. al, 1979) used in developing the oral and inhalation values for the Health Canada report (Health Canada, 2006) is the exact same as that used for the oral toxicity reference value used in the USEPA study (USEPA, 2001). This did not represent a newer scientific study.
 - j. Information provided by Health Canada (Health Canada, 2006) was based on newer, accepted protocols for development of the TRV than was available in the USEPA 1987 study. In addition, the information available for the vapour inhalation pathway was not a priority for review by any agency that is considered a primary reference source for the pathways specified and the SWGCSA was not expecting this to be updated soon by any relevant agency.
5. Based on reviewing the most up to date information, the inhalation unit risk be removed from the carcinogenic TRV column of the Alberta Tier 1 Guidelines (AEP, 2016).
 6. The reference to the USEPA (2001) document was also removed. The oral TDI reference dose was changed from a value of 0.01 mg/kg BW/day to 0.0062 mg/kg BW/day to reflect the TDI derived in the supporting documentation for the Health Canada Drinking Water guideline (Health Canada, 2006). The reference to USEPA (2001) was replaced by a reference to Health Canada (2006).
 7. The inhalation tolerable concentration was extrapolated from the oral reference value from Health Canada (2006) and used until a more appropriate pathway specific threshold value is derived. The Tolerable Concentration in air became 0.028 mg/m³ rather than the value of 0.04475 mg/m³.

2.4 References

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3. Tetrachloroethylene (Perchloroethylene, Tetrachlorethene (PCE))

3.1 Summary

During the review of the 2014 Alberta Tier 1 Soil and Groundwater Quality Guidelines, the Human Health TRVs for tetrachloroethylene (PCE) were reviewed due to recent updates by the USEPA (2012) and Health Canada (2015). Both of these publications were considered to be primary reference sources under section 5.1.1.

Based on a review of current information, the non-carcinogenic oral tolerable daily intake (TDI) was changed from 0.014 mg/kg-d (Health Canada 2004) to 0.0047 mg/kg-d (Health Canada, 2015). The non-carcinogenic inhalation tolerable concentration (TC) of 0.36 mg/m³ (Health Canada 2004) was changed to 0.04 mg/m³ (USEPA 2012). Based on this review, the recommended carcinogenic non-threshold value was determined to result in a higher oral TDI than the non-carcinogenic threshold value (0.0068 mg/kg-d vs. 0.0047 mg/kg-d) (Health Canada, 2015). Similarly, the recommended carcinogenic non-threshold value would result in the same inhalable tolerable concentration for PCE as the recommended threshold value (0.04 mg/m³). The non-threshold value was removed from the Alberta Tier 1 and Tier 2 Guidelines (AEP, 2016a,b).

Based on section 6.1, point 7, a rationale for the decision is required since the recommendation is based on newer information but uses lower ranking primary sources to supersede a higher ranking primary source for the same information.

3.2 Rationale for the Review

Under section 6.1 point 7, it was determined that a review of PCE was necessary for the following reasons:

1. During the review of the PCE TRVs, it was determined that the existing values were outdated and based on older information than was available during the USEPA (2012) and the Health Canada (2015) reviews.
2. Newer scientific research was considered in determining the risk associated with tetrachloroethylene regarding the mode of action for PCE.
3. It was further noted that Health Canada (2015) upgraded the cancer classification of PCE from Group 3 “*possibly carcinogenic to humans*” to a Group 2A, “*probably carcinogenic to humans*” classification. This had not been considered during earlier assessments and was deemed to represent a potential human health risk that was not being considered when determining the Alberta Tier 1 2014 Guideline (ESRD, 2014).

3.3 Key Findings

1. In 2015, Health Canada upgraded the cancer classification of PCE to PCE from Group 3 “*possibly carcinogenic to humans*” to a Group 2A, “*probably carcinogenic to humans*” (Health Canada, 2015). Currently, GOA follows the Health Canada policy (Health Canada, 1994) regarding the use of the non-threshold approach for calculating carcinogenic effects to humans; this means that the cancer risks for PCE needed to be considered in updating the Alberta Tier 1

Guideline. According to the policy, for a Group 2A compound, both carcinogenic and non-carcinogenic effects needed to be evaluated and the lower of the two was to be adopted in the guidelines.

2. There were two updates for tetrachloroethylene that were not considered in the 2014 Alberta Tier 1 Guidelines (ESRD, 2014) but are considered primary reference sources: Health Canada (2015) and USEPA (2012).
3. According to the section 6.1 ,point 3, of this document, where there is no other rationale, primary reference sources that are higher ranking for the pathway being considered, should be considered preferentially for updating Alberta Tier 1 Guidelines. Health Canada (2015) was considered as authoritative for the drinking water pathway and that the USEPA (2012) was authoritative for the vapour inhalation pathway.
4. For the oral route of exposure, both Health Canada (2015) and USEPA (2012) provided TRVs with associated rationale. Based on section 6.1 of this guidance document, Health Canada was considered a higher ranking source of information and was considered preferentially over the USEPA value. The Federal-Provincial-Territorial Committee on Drinking Water does not have a mandate for dealing with the inhalation route of exposure. The same information however, was reviewed in 2012 by the USEPA and it appears that similar information was used in making the final recommendation(s). Accordingly, the USEPA (2012) was used for the inhalation route of exposure.
5. In reviewing Health Canada (2015), it was noted that a value could be derived for the inhalation pathway since the principal study and point of departure used for the oral TRV were based on the same inhalation study (Cavalleri et al., 1994) that was used to derive the TC used by the USEPA (USEPA 2012). Health Canada used a route-to-route extrapolation via physiologically based pharmacokinetic modelling to derive the oral TDI from the inhalation study.
6. It is, however, noted that an inhalation value from Health Canada would only have been directly peer-reviewed in the context of deriving a drinking water criteria and therefore would have not gone through the same peer review process and public scrutiny as with the USEPA (2012). Despite this, derivation of a Health Canada TDI would result in a very similar TDI value to that recommended by the USEPA (2012).
7. During the review, it was noted that the previous studies used to determine the 2014 Alberta Tier 1 Guideline did not appropriately address the current understanding of carcinogenicity with respect to PCE. The reclassification was considered a risk that was then addressed when developing the current Alberta Tier 1 Guidelines (AEP, 2016a).
8. During the review, it was noted that Health Canada may review and adopt a new TRV for the vapour inhalation pathway for PCE. Internal discussions with Health Canada during the review indicated that preliminary review agrees with the conclusions of USEPA in 2012.
9. Given that the current TRV did not appropriately address the issue associated with the reclassification of PCE, the TRV was updated based on USEPA (2012). This decision will be re-evaluated if Health Canada completes their review.

3.4 References

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